UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/092,919	03/08/2002	Kjell Olmarker	003300-914	1488

7590 11/03/2004

Benton S. Duffett, Jr.
BURNS, DOANE, SWECKER & MATHIS, L.L.P.
P.O. Box 1404
Alexandria, VA 22313-1404

EXAMINER	
MONDESI, ROBERT B	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 11/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/092,919	OLMARKER, KJELL	
	Examiner	Art Unit	
	Robert B Mondesi	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *August 08, 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *11-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 23-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to restriction requirement

Applicant's election with traverse of Invention L, **Claims 1-10, 23-25** in the amendment filed September 08, 2004 is acknowledged. The traversal is on the ground(s) that the Groups are closely related and a search of the entire application can be made without a serious burden. This is not found persuasive because the compounds and compositions that the applicants propose to use in the methods of the invention are not closely related. In fact not only they are classified in a variety of different classes and subclasses but they also have different functions and effects.

Therefore the requirement is still deemed proper and is made FINAL. **Claims 1-25** are pending in this application. **Claims 11-22** are withdrawn from further consideration by the Examiner because these Claims are drawn to non-elected inventions. **Claims 1-10 and 23-25** are currently under examination.

Priority

The current application filed on March 08, 2002 claims priority to foreign application, SWEDEN 0200667-7 filed on March 05, 2002. A certified translation of foreign document SWEDEN 0200667-7 has not been provided.

Information Disclosure Statement

The IDS filed August 26, 2003 has been received and is signed and considered, a copy of the PTO 1449 is attached to the following document.

Specification

The disclosure is objected to because of the following informalities:

The use of the trademarks APOZEPAM, MEBUMAL VET (page 5, lines 31-32) HYPNODIL, KETALAR, STERSNIL (page 6, lines 20-24), HUMICADE, ROQUININEX, ARIFLO, ORTHEGEN, ORTHOKIN (page 10, line 3 and 34) have been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10 and 23-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir.1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation

needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the breadth of the claims, (2) the nature of the invention, (3) the state of the prior art, (4) the relative skill of those in the art, (5) the predictability or unpredictability of the art, (6) the amount or direction or guidance presented, (7) the presence or absence of working examples, and (8) the quantity of experimentation necessary. Although the quantity of experimentation alone is not dispositive in a determination of whether the required experimentation is undue, this factor does play a central role. For example, a very limited quantity of experimentation may be undue in a fledgling art that is unpredictable where no guidance or working examples are provided in the specification and prior art, whereas the same amount of experimentation may not be undue when viewed in light of some guidance or a working example or the experimentation required is in a predictable established art. Conversely, a large quantity of experimentation would require a correspondingly greater quantum of guidance, predictability and skill in the art to overcome classification as undue experimentation. In Wands, the determination that undue experimentation was not required to make the claimed invention was based primarily on the nature of the art, and the probability that the required experimentation

would result in successfully obtaining the claimed invention. (Wands, 8 USPQ2d 1406). Thus, a combination of factors which, when viewed together, would provide an artisan of ordinary skill in the art with an expectation of successfully obtaining the claimed invention with additional experimentation would preclude the classification of that experimentation as undue. A combination of Wands factors, which provide a very low likelihood of successfully obtaining the claimed invention with additional experimentation, however, would render the additional experimentation undue.

1.Breadth of the claims.

In regards to the method of the invention and the breadth of the claims the broadest interpretation that applies is a method of preventing scar tissue or adhesion formation wherein an effective therapeutic amount of a peptide or a substance derived from lactoferrin is administered to a patient in need thereof.

2. The nature of the invention.

The invention is a method of prevention of scar tissue or adhesion formation using a peptide or a substance derived from lactoferrin.

3. The state of prior art.

In regards to the treatment of scar tissue and adhesion formation, the prior art provides evidence for the treatment of scar tissue and adhesion formation using a peptide or a substance derived from lactoferrin (Reuben et al.) However, a method of prevention of scar tissue and adhesion formation is not disclosed in the previous studies of such topic.

4. The relative skill in the art.

The relative skill in the art as it relates to the administering of therapeutic polypeptides used for the treatment, inhibition, prevention or amelioration of pancreatic disorder is characterized by that of a M.D. or Ph. D. level individual.

5. The level of predictability in the art.

Since there is not much known about the nature of preventing scar tissue and adhesion formation using a peptide or a substance derived from lactoferrin, one skill in the art would not be able to readily anticipate the effect of administering the a peptide or a substance derived from lactoferrin in regards to preventing scar tissue and adhesion formation.

6. The amount of guidance present.

The applicant has not provided any guidance for a method of prevention of scar tissue and adhesion formation using a peptide or a substance derived from lactoferrin. The applicant has shown guidance as to how the method of the invention can be used to treat scar tissue and adhesion formation using a peptide or a substance derived from lactoferrin.

7. The existence of working examples.

The specification in pages 14-17 provides examples that show how a peptide or a substance derived from lactoferrin can be used for the treatment of scar tissue or adhesion formation. However, the specification does not provide any information or examples that show to person skill in the art how the applicants' invention can be used

to prevent scar tissue or adhesion formation using a peptide or a substance derived from lactoferrin.

8. The quantity of experimentation necessary.

In the case of preventing scar tissue or adhesion formation using a peptide or a substance derived from lactoferrin more experimentation would be required to practice the invention since the specification has not shown to a person skill in the art how the method of the invention can be used to prevent scar tissue or adhesion formation.

Due to the large quantity of experimentation necessary to provide evidence that the claimed method of the invention will prevent scar tissue or adhesion formation, the lack of guidance presented in the specification regarding the same, the absence of a working example directed to same, the unpredictable nature of the invention with regards to prevention, the state of the prior art not providing any evidence for any methods of prevention for scar tissue or adhesion formation, and the breath of the claims which fails to provide particular steps involved in the prevention scar tissue or adhesion formation, the specification fails to teach the skilled artisan in the art how to make and use the invention.

Note to the applicant, an amendment to the claims removing the word **preventing** will overcome this rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-10 and 23-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Reuben et al. United States Patent Application Publication US 2002/0072596.

Reuben et al. teach a method of treating hypertophic scars and keloids comprising the step of administering peptides derived form lactoferrin (page 4, section 0041; page 63, section 05900. Reuben et al. teach further that the lactoferrin derived peptides of their invention can be used in a method of treatment for post traumatic tissue injury caused by surgery or a pathological condition with scar formation wherein the scar formation is caused by a vascular disease (page 63, 0590, 0591, 0593) Reuben et al. also teach that peptides derived form lactoferrin can be administered locally (page 63, section 0594 and 0595). Reuben et al. teach that peptides derived from lactoferrin can be used to modify the activity of molecules such as TNF and IL-1 (page 28, section 0024). Thus Reuben et al. teach all the elements of **claims 1-10 and 23-25** and these claims are anticipated under 35 USC 102(b).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert B Mondesi
RBM
10-26-05

ROBERT A. WAX
PRIMARY EXAMINER
Art Unit 1653